

FILED

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

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CLERK US DISTRICT COURT  
ALEXANDRIA, VIRGINIA

**Abbott Cardiovascular Systems Inc.**  
3200 Lakeside Drive, S314  
Santa Clara, CA 95054-2807

Plaintiff,

v.

**The Honorable David J. Kappos**  
**Under Secretary of Commerce for**  
**Intellectual Property and Director of the**  
**United States Patent and Trademark Office**  
Office of General Counsel  
U.S. Patent and Trademark Office  
P.O. Box 14557, Arlington, VA 22215  
Madison Building East, Room 10B20  
600 Dulany Street, Alexandria, VA 22314

Defendant.

Civil Action No.

1:12cv1382  
GBL/JFA

COMPLAINT

Abbott Cardiovascular Systems Inc. ("Abbott") respectfully states as follows for its Complaint against the Honorable David J. Kappos ("Defendant"):

1. Abbott is the assignee and owner of US Patent No. 8,192,752 ("the '752 Patent"), entitled "Coatings for Implantable Devices Including Biologically Erodable Polyesters and Methods for Fabricating the Same," a true and correct copy of which is attached as Exhibit A. Abbott brings this action under the Administrative Procedure Act (5 U.S.C. §§701-706) and 35 U.S.C. §154, seeking the Court's review of an erroneous patent term adjustment determination by the United States Patent and Trademark Office ("USPTO"). In particular, Abbott seeks judgment that the patent term adjustment for the '752 patent be changed from 1,689 days to 2,599 days.

### **THE PARTIES**

2. Abbott is a California corporation with a principal place of business located at 3200 Lakeside Drive, S314, in Santa Clara, California.

3. Defendant is the Under Secretary of Commerce for Intellectual Property and Director of the USPTO, and is sued here in his official capacity.

### **JURISDICTION AND VENUE**

4. This Court has jurisdiction pursuant to 28 U.S.C. §§1331, 1338(a) and 1361; 35 U.S.C. §154(b)(4)(A); and 5 U.S.C. §§701-706.

5. Venue is proper (and indeed mandatory) in this District pursuant to 35 U.S.C. §154(b)(4)(A).

6. This Complaint is timely filed pursuant to 35 U.S.C. §154(b)(4)(A).

### **FACTS**

7. On November 21, 2003, Yiwen Tang and Stephen D. Pacetti, inventors of the '752 patent and employees of Abbott (collectively "Applicants"), filed patent application no. 10/719,516 ("the '516 application"). *See* '752 patent at 1 (cover page).

8. On March 20, 2007, the USPTO mailed its first office action regarding the '516 application under 35 U.S.C. §132.

9. The USPTO mailed its first final rejection on July 27, 2007. On October 25, 2007, Applicants appealed the first final rejection to the USPTO Board of Patent Appeals and Interferences ("BPAI").

10. On January 3, 2008, Applicants abandoned the first Notice of Appeal by filing a Request for Continuing Examination ("RCE") under 35 U.S.C. §132(b). In accordance with the first RCE, the USPTO mailed a non-final rejection on April 18, 2008. The USPTO ultimately issued a second final rejection of the '516 application.

11. Applicants appealed the second final rejection of the '516 application to the BPAI on November 2, 2009 ("the second Notice of Appeal"). On August 17, 2011 – 654 days later – the BPAI issued its decision on appeal reversing the second final rejection.

12. The '516 application issued as the '752 patent on June 5, 2012 – 2,023 days after the three-year period prescribed in section 154(b)(1)(B), and 1,685 days after Applicants filed the first Notice of Appeal. The '752 patent is not subject to a terminal disclaimer.

13. Abbott is the assignee of all right, title and interest in the '752 patent.

14. The face of the '752 patent reflects a patent term adjustment under 35 U.S.C. §154(b)<sup>1</sup> of 1,689 days.

15. In 35 U.S.C. §154(b)(1)(B), entitled “Guarantee of no more than 3-year pendency,” Congress guaranteed that “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States . . . the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.” This “one-for-one” day extension is subject to several exceptions, including “any time consumed by continued examination of the application requested by the applicant under section 132(b).” 35 U.S.C. §154(b)(1)(B)(i).

16. The USPTO interprets section 154(b)(1)(B) to eliminate the one-for-one day extension during the pendency of an of appellate review – whether before or *after* three years have elapsed in the application process. This interpretation is expressed in the USPTO’s American Inventor’s Protection Act of 1999-Comparison Chart, which the USPTO makes available at [http://www.uspto.gov/patents/law/aipa/presentation/comparison\\_of\\_cpa\\_practice.jsp](http://www.uspto.gov/patents/law/aipa/presentation/comparison_of_cpa_practice.jsp) and a true and correct copy of which is attached as Exhibit B. In the Comparison Chart the USPTO states that “filing a RCE cuts-off the applicant’s ability to accumulate any additional patent term adjustment against the three-year pendency provision, but does not otherwise affect patent term adjustment.” The USPTO’s policy regarding patent term adjustments appears to be the same for RCEs and appellate review.

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<sup>1</sup> Sometimes referred in this Complaint to as “section 154(b).”

17. In calculating the patent term adjustment for purposes of the '752 patent, the USPTO – relying on its interpretation of section 154(b)(1)(B) – did not take into account the additional delay by the USPTO following Applicant's filing of the first Notice of Appeal on October 25, 2007, which was more than three years after the application filing date.<sup>2</sup> In particular, the USPTO's patent term adjustment does not take into account the 1,685-day period from when Applicants filed the first Notice of Appeal to the date of issue. *See* USPTO PAIR Patent Term Adjustment Calculation for the '752 patent, a true and correct copy of which is attached as Exhibit C.

18. This Court recently held that the USPTO's patent term adjustment interpretation is erroneous under section 154(b)(1)(B) for events occurring more than three years after the application filing date. In *Exelixis, Inc. v. Kappos*, Case No. 1:12-cv-00096, 2012 U.S. Dist. LEXIS 157762 (Nov. 1, 2012) (attached as Exhibit D), the Court held in pertinent part that

Especially notable about this reading of [section 154(b)(1)(B)], which is commanded by the provision's plain and unambiguous language, is that it does not address the filing of an RCE after the expiration of the three year clock. To be sure, the provision makes clear that the clock is tolled for the processing of an RCE filed before the three year clock runs out, but the provision does not refer to or mention RCE's filed after the three year clock has run. Instead, *subparagraph (B) makes clear that once the three year clock has run, [patent term adjustment] is to be awarded on a day for day basis regardless of subsequent events.*

2012 U.S. Dist. LEXIS 157762 at \*18 (emphasis added). In awarding summary judgment in favor of the plaintiff-patent owner and against the USPTO, the Court thus concluded:

In sum, the plain and unambiguous language of subparagraph (B) requires that the time devoted to an RCE tolls the running of the three year clock if the RCE is filed within the three year period. *And, put simply, RCE's have no impact on [patent term adjustment] if filed after the three year deadline has passed.* The USPTO's arguments to the contrary are not persuasive and, accordingly, the USPTO's interpretation of subparagraph (B) must

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<sup>2</sup> The USPTO also did not account for the time period following Applicants' RCE, either, although this time period is wholly subsumed by the period following the first Notice of Appeal.

be set aside as “not in accordance with law” and “in excess of [its] statutory . . . authority” pursuant to 5 U.S.C. § 706(2)(A) and (C).

*Id.* at \*26 (emphasis added).

19. While *Exelixis* addressed the USPTO’s day-for-day patent term adjustment policy for RCEs under 35 U.S.C. §154(b)(1)(B)(i), “subparagraph (B) makes clear that once the three year clock has run, [patent term adjustment] is to be awarded on a day for day basis regardless of subsequent events.” 2012 U.S. Dist. LEXIS 157762 at \*18. In other words, following the three-year anniversary of an application, the patent term adjustment accrues regardless of whether the applicant files an RCE under section 154(b)(1)(B)(i) and any proceeding covered by section 154(b)(1)(B)(ii) – including a request for appellate review under that subsection. As properly construed by this Court in *Exelixis*, therefore, the USPTO erred in not awarding a patent term adjustment for the entire period following Applicants’ first Notice of Appeal.

20. Under 35 U.S.C. §154(b)(4)(A), “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action”

#### **CLAIM FOR RELIEF**

21. Abbott incorporates by reference the allegations contained in paragraphs 1-20 above as if fully set forth herein.

22. The USPTO determined that the patent term adjustment for the ’752 patent is 1,689 days.

23. This determination is erroneous because it fails to include within the adjustment the entire time period from Applicants’ October 25, 2007 first Notice of Appeal to the ’752 patent’s June 5, 2012 issue date, even though Applicants’ first Notice of Appeal fell outside the three-year deadline in section 154(b).

24. This Court held in *Exelixis* that, as a matter of law, the events enumerated in section 154(b)(1)(B) “have no impact on [patent term adjustment] if filed after the three year

deadline has passed.” 2012 U.S. Dist. LEXIS 157762 at \*26. Applicants filed the first Notice of Appeal here well after the three-year deadline expired.

25. Because it failed to include the entirety of the 1,685-day period following the first Notice of Appeal within the patent term adjustment, the USPTO’s patent term adjustment is “‘not in accordance with law’ and [is]’ in excess of [its] statutory . . . authority’ pursuant to 5 U.S.C. § 706(2)(A) and (C).” *Exelixis*, 2012 U.S. Dist. LEXIS 157762 at \*26.

26. After adjusting for additional overlap created by the inclusion of the missing 1,685-day period, the correct patent term adjustment for the ’752 patent is 2,599 days.

### PRAYER

Abbott accordingly prays that the Court:

A. Enter judgment for Abbott changing the period of the patent term adjustment for the ’752 patent from 1,689 days to 2,599 days, and requiring that Defendant alter the terms of the ’752 patent to reflect 2,599 days of actual patent term adjustment; and

B. Grant such other and further relief as may be equitable and just.

Dated: November 30, 2012

Respectfully submitted,

By: 

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